

## **REMARKS**

### ***Claim Amendments***

New compound claims 23-32 have been added by the above amendments, each claim being directed to a single preferred disclosed/exemplified compound *per se* within the scope of formula (I) of claim 1, or to a pharmaceutically acceptable salt thereof. Each named compound is disclosed *per se* in the original specification and claims of the PCT application, and the specification provides at page 17, lines 9-13 that the compounds of formula (I) can be converted to a pharmaceutically acceptable salt, for example an acid addition salt “such as a hydrochloride, hydrobromide, phosphate, acetate, fumarate, maleate, tartrate, citrate, oxalate, methanesulphonate or *p*-toluenesulphonate, or an alkali metal salt such as a sodium or potassium salt.” In particular, support for new claims 23-32 can be found as follows:

- The compound of **claim 23** is named *per se* as the 6th named compound in the list of preferred compounds beginning at the bottom of page 5, and its salt form is supported at page 17, lines 9-13, and more specifically in Example 6f) and the 6th named compound of *original* claim 10.
- The compound of **claim 24** is named *per se* as the 7th named compound in the list of preferred compounds beginning at the bottom of page 5 and in Example 29c) and d), and its salt form is supported at page 17, lines 9-13, and more specifically in Examples 7 and 76, and the 7th named compound of *original* claim 10.
- The compound of **claim 25** is named *per se* as the 8th named compound in the list of preferred compounds beginning at the bottom of page 5, and its salt form is supported at page 17, lines 9-13, and more specifically in Example 8 and the 8th named compound of *original* claim 10.
- The compound of **claim 26** is named *per se* as the 9th named compound in the list of preferred compounds beginning at the bottom of page 5 and its salt form is supported at page 17, lines 9-13, and more specifically in Example 9 and the 9th named compound of *original* claim 10.

- The compound of **claim 27** is named *per se* as the 12th named compound in the list of preferred compounds beginning at the bottom of page 5, and its salt form is supported at page 17, lines 9-13, and more specifically in Example 12 and the 12th named compound of *original* claim 10.
- The compound of **claim 28** is named *per se* as the 30th named compound in the list of preferred compounds beginning at the bottom of page 5, in Example 30 and the 30th named compound of *original* claim 10, and its salt form is supported at page 17, lines 9-13, and more specifically in Example 30c).
- The compound of **claim 29** is named *per se* as the 52nd named compound in the list of preferred compounds beginning at the bottom of page 5, in Example 52 and the 52nd named compound of *original* claim 10, and its salt form is supported at page 17, lines 9-13.
- The compound of **claim 30** is named *per se* as the 54th named compound in the list of preferred compounds beginning at the bottom of page 5, in Example 54 and the 54th named compound of *original* claim 10, and its salt form is supported at page 17, lines 9-13.
- The compound of **claim 31** is named *per se* as the 59th named compound in the list of preferred compounds beginning at the bottom of page 5, in Example 59 and the 59th named compound of *original* claim 10, and its salt form is supported at page 17, lines 9-13.
- The compound of **claim 32** is named *per se* as the 66th named compound in the list of preferred compounds beginning at the bottom of page 5, in Example 66 and the 66th named compound of *original* claim 10, and its salt form is supported at page 17, lines 9-13.

Clearly no new matter has been added by new claims 23-32, and they each claim a species within the genus of claim 1 and therefore fall within the scope of the elected invention. Accordingly, entry of new claims 23-32 is believed to be in order and is respectfully requested.

Following entry of the above amendments, claims 1-4, 6, 10, 12 and 23-32 are pending in this application with claims 11, 13 and 20-22 being withdrawn and awaiting rejoinder.

***Claim Rejections - Obviousness-Type Double Patenting***

Claims 1-4, 6, 10 and 12 have been rejected on the ground of “non-statutory” double patenting over Claims 1-5, 10 and 26 of U.S. Patent No. 6,881,754 (hereinafter “the ‘754 Patent”), which issued from the parent of the present application. In making this rejection the Examiner asserts:

The scope of the subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: **Claim 1** of the instant application is a sub-genus of **Claim 1** in the patent, and therefore, all limitations of the current application are supported by the parent US Patent. Additionally, **Claims 2-4, 6 and 12** are relatively identical to **Claims 2-5 and 26** of the patent. Furthermore, there are several overlapping species in **Claim 10** of the instant application and **Claim 10** of the patent. For example, the elected species is located in column 65, line 56.

(Action at page 4).

While this ground for rejection has been rendered moot by the Terminal Disclaimer filed herewith, Applicants wish to correct the record with respect to certain of the statements made by the Examiner.

First of all, the Examiner is reminded that obviousness-type double patenting can be based only on what is claimed in the reference patent relative to what is claimed in this application. The specification disclosure may be referred to in limited circumstances to interpret the meaning of a claim, but the specification disclosure cannot function as a basis for an obviousness-type double patenting rejection. Therefore, the Examiner’s statements such as “the subject matter claimed in the instant application is fully disclosed in the patent,” and “all limitations of the current application are supported by the parent US Patent” are not relevant or appropriate to an obviousness-type double patenting rejection.

Moreover, it is apparent from the Examiner's characterization of what is claimed in the '754 Patent that he is looking at the erroneous, originally issued claims, and not at the *actual corrected claims after the Certificate of Correction issued on July 12, 2005*. Thus, contrary to the implication of the Examiner's assertions, the subject matter of the presently pending claims is not fully covered by the *corrected* claims of the '754 Patent.

The certificate of correction was requested in the '754 Patent because, due to patent office errors, the claims that initially issued did not reflect certain amendments that had been filed during prosecution. Thus, for example, the *actual* claims of the '754 Patent are such that the group R<sup>5</sup> *does not represent a hydrogen atom*. In contrast, the presently pending claims specify that R<sup>5</sup> can be hydrogen and that the group X represents NR<sup>13</sup>. A consequence of the correction to the '754 Patent claims is that the present claims cover exemplified compounds that are not covered by the claims of the '754 Patent. These include the elected species, 2-chloro-5-[3-(cyclohexylamino)propyl]-N-(tricyclo[3.3.1.1<sup>3,7</sup>]dec-1-ylmethyl)-benzamide (the compound of Example 52), which the Examiner incorrectly states is recited in claim 10 of the '754 Patent. This compound is *not* covered by claim 10 of the '754 Patent after being corrected by the certificate of correction (*i.e.*, by the deletion of column 65, lines 56-57).

Nevertheless, in order to expedite the prosecution of this application to allowance, a Terminal Disclaimer relative to the '754 Patent is submitted herewith. In so doing, however, Applicants do not acknowledge the correctness of the Examiner's position. In that regard, it should be noted that under MPEP 804.02, the filing of this terminal disclaimer is not intended to be an admission that Applicants' claimed subject matter is not patentably distinct over the claimed subject matter in the referenced patent. Rather, the filing of the terminal disclaimer "simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection" (citing *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870 (Fed. Cir. 1991)).

#### ***Request for Rejoinder of Withdrawn Claims***

Inasmuch as sole ground for rejection in this application was based on obviousness-type double patenting over the '754 Patent, and this ground for rejection has been obviated

by the Terminal Disclaimer, all product claims should now be allowable. As the Examiner noted at page 8 of the October 31, 2005 Action in which the restriction requirement was made, "rejoinder of product claims with process claims [*i.e.*, method of use and process for making claims] commensurate in scope with the allowed product will occur following a finding that the product claims are allowable." The Examiner there further advised Applicants "that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims."

All product claims should now be allowable, and process for making claim 11 and 13 and method of use claims 20-22 remain dependent on the compound scope of allowable claim 1. According, rejoinder of withdrawn claims 11, 13 and 20-22 is now appropriate and is respectfully requested.

#### ***Correction of Inventorship***

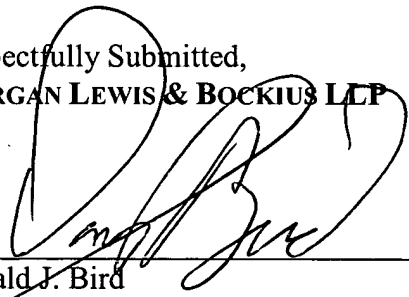
Applicants' Petitioned on November 10, 2004, for a correction of inventorship to reflect the change of claim scope by reason of the Preliminary Amendment filed March 31, 2004, which Petition was granted on March 1, 2006. The "grant" document states that "the application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected." As of this date Applicants have not received a corrected filing receipt and no activity whatsoever is shown in PAIR with respect to this application subsequent to the March 1, 2006 mailing of the Grant of the Petition. It is respectfully requested that the Examiner initiate and/or follow through on whatever further action may be required to correct the PTO records and otherwise put into effect the already granted correction of inventorship so that the correct inventorship is shown on the patent that will issue from this application.

***Conclusion***

All grounds for rejection of the product claims having been met and overcome, it is believed appropriate and respectfully requested that the non-elected, withdrawn claims be rejoined in this application, and that a Notice of Allowance of all claims be issued.

EXCEPT for issue fees payable under 37 C.F.R. § 1.18, the Director is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully Submitted,  
**MORGAN LEWIS & BOCKIUS LLP**



Date: May 23, 2006  
Morgan Lewis & Bockius LLP  
Customer No. 09629  
1111 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004  
Tel. No.: 202-739-3000  
DJB:

By:

Donald J. Bird  
Registration No. 25,323  
Tel. No.: (202) 739-5320  
Fax No.: (202) 739-3001